REMARKS

Reconsideration of this application is requested. Claims 13-34 are active in the application subsequent to entry of this Amendment.

Attached is an evidentiary declaration made by inventor Tossavainen on May 23, 2003 as well as data sheets.

It is proposed to amend the claims in order to more particularly point out and distinctly claim that which applicants regard as their invention, to direct the claims to preferred aspects of the invention and to further characterize the method of the invention generally.

In their specification applicants describe the preferred embodiment of the invention in which the ultra and dia-filtration is carried out either before or after or before and after the adsorption resin treatment. Thus in a preferred embodiment resin treatment with the indicated macroporous adsorption resin is combined with one or two ultra and dia-filtration treatments; see page 6, lines 23-24. Claim 13 is amended to clarify and point out this aspect of the description of the invention.

In addition, the subject matter of claim 14 is included as an optional step in the method. Also, the steps of the method are introduced by "consisting essentially of" terminology so that additional steps such as enzymatic hydrolysis and a second resin treatment with a hydrophobic adsorption resin (as required in the removal of bovine insulin in the prior art) are excluded from the procedures of claim 13. Finally, the macroporous adsorption resin is defined as having a pore size of a particular range (see page 5, lines 13-16 of the specification) thus the range of claim 17 has been incorporated into claim 13. Claim 17 is amended to refer to the pore size range for Amberlite XAD 7 as described in the specification at page 5, line 15.

In the Official Action all claims stand rejected as allegedly being anticipated or obvious over Vaarala et al (WO 98/48640). The present applicants are well familiar with

this document as four of the applicants in the citation are also among the five inventors listed in the subject application as inventors.

The Official Action argues that the same resins are claimed in the present application as are used in the '640 reference; see page 2, last sentence. This is not correct.

The examiner has rejected claims 13-34 as anticipated by or as obvious over Vaarala et al (WO 98/48640). It is argued that the strong cation exchange resin (Amberlite C-20) utilized in Example 1 (page 8 in WO 98/48640) is a styrene based adsorption resin. This is not the case. It should be noted that there are many kinds of Amberlite resins – see Hawley's Condensed Chemical Dictionary, 13th Edition (1997), page 47, copy attached. E.g. Amberlite C-20 and Amberlite IR-120 are both gel type strong cation exchange resins without any information of pore size. However, these two resins are not macroporous adsorption resins as required by applicants' claims.

On the other hand e.g. Amberlite XAD 7 which is used in the subject patent application is a macroporous adsorption resin and its pore size is between 450 and 500 Å (see page 5 in WO 00/18251). Thus contrary to the assertion in the last line of page 2 of the Action, the resins used in Vaarala et al (WO 98/48640) and in the subject patent application are different resins. There is no anticipation.

To anticipate a claim, a single reference must disclose the claimed invention with sufficient clarity to prove its existence in the prior art. *Motorola Inc. v. Interdigital Technology Corp.*, 43 USPQ2d 1481, 1490 (Fed. Cir. 1997). Anticipation rejections are only proper when the "claimed subject matter is identically disclosed or described in 'the prior art,' without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." *In re Arkley*, 172 USPQ 524, 526 (CCPA 1972); *see also Akzo N.V. v. International Trade Commission*, 1 USPQ 2d 1241, 1246 (Fed. Cir. 1986); *Ex parte Lee*, 31 USPQ 2d 1105, 1108 (BPAI 1993). Every element of the challenged claim must be disclosed within this single reference. *PPG Industries Inc. v. Guardian Industries Corp.*, 37 USPQ2d 1618, 1624

(Fed. Cir. 1996). Absence from the reference of any claimed element negates anticipation *Kloster Speedsteel AB v. Crucible Inc.* 23 USPQ 160 (Fed. Cir. 1986).

Thus, applicants' claims are patentable over the cited reference since it fails to disclose each element of applicants' claims.

Nor are applicants' claims "obvious" over the disclosure of WO 98/48640. Applicants have conducted comparative tests concerning effectiveness of certain resins in removing of bovine insulin (BI) from a fat-free test solution. These tests were carried out using (A) one strong cation exchange resin used in WO 98/48640 and (B) two macroporous adsorption resins used in the subject patent application. Amberlite-IR-120 was used in these tests as a strong cation exchange resin used in WO 98/48640 (A). Both Dowex XUS 40285.00 and Amberlite XAD 7 were used in these tests as macroporous adsorption resins falling within the claims of the subject patent application (B).

Attached for the examiner's review are product data sheets on Amberlite IR 120 Na and Dowex XUS 40285.00 ion exchange resins.

In the tests the test solution was fat-free and contained 0.01 mg BI/ml in water. The pH of the test solution was adjusted to 4.0, 5.8 or 6.4 by using 0.06M citric acid buffer. This buffer has same conductivity as normal sweet whey (5 mS cm^{-1}). Each test solution was contacted at room temperature with different resins in a mixing vessel, i.e. in an Erlenmeyer flask on a shaker. The weight ratio of the bovine insulin to be removed from the solution to the resin was about 1:20 000.

The degree of bovine insulin (BI) removal from the above-mentioned test solution with above-mentioned three resins were following:

Resin	Degree of BI removal (%) pH 4.0	pH 5.8	pH 6.4
Macroporous adsorption resin (B): Amberlite XAD 7	100	100	100
Macroporous adsorption resin (B): Dowex XUS 40285.00	100	100	100
Gel type strong cation exchange resin (A): Amberlite IR-120	58.1	22.2	0

From these data it can be concluded that when using a macroporous adsorption resin used in the subject patent application (B) the degree of bovine insulin (BI) removal from the fat-free test solution was 100%. However, when using a strong cation exchange resin used in WO 98/48640 (A) the degree of bovine insulin (BI) removal from the fat-free test solution was much lower, i.e. only from 0% to 58.1%.

Thus the method of the present invention for removing bovine insulin from a certain liquid fat-free material using only one resin, i.e. a certain macroporous adsorption resin, is much more practical than the multi-step process of WO 98/48640 using two different resins, i.e. a strong cation exchange resin in step (a) and a hydrophobic adsorption resin in step (d) after enzymatic hydrolysis in step (c1).

Submitted with this response is the declaration of Olli Tossavainen who is an inventor of both the present application and also of the citation relied upon. His declaration verifies the information presented above and establishes reasons why the claims of the present application are patentable over the disclosures of WO 98/48640. Careful consideration of this evidence is requested.

Reconsideration, entry of this Amendment as well as the attached evidence and allowance are solicited.

Respectfully submitted,

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